



Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax orthomolecularproducts.com

Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

## Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Gastrointestinal Support, Immune Health

Dietary Ingredients: Sweet Wormwood (Aerial Portion), Olive Leaf Extract (Standardized to contain 20% Oleuropein), Oregano Leaf Extract 10:1, Grapefruit Seed Extract (Citricidal), Berberine Sulfate, Goldenseal Root Extract (Standardized to contain 5% Alkaloids), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Paracid Forte

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

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Ortho Molecular Products

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Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715 342.9881 Phone 800.332.2351 715 342.9866 Fax orthomolecularproducts.com Attachment of Paracid Forte Labels

Suggested Use: As a dietary supplement, 2-3 capsules three times per day or as recommended by your health care professional Formulated to be free of allergens derived from: Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. Do not consume if you are pregnant or nursing. Consult your physician for further information. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion.

KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE, KEEP OUT OF REACH OF CHILDREN. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged. Label ID L-OMP100-814090-B





Also Excellent for:



Paracid Forte



Supplement Facts

Serving Size 1 Capsule Servings Per Container: 90

Amount Per % Daily Serving Sweet Wormwood (Aerial Portion)
Olive Leaf Extract 150 mg (Standardized to contain 20% Oleuropein)
Oregano Leaf Extract 10:1 70 rr 70 mg Grapetruit Seed Extract (Citricidai®) 65 mg Berberine Sulfate 50 mg Goldenseal Root Extract 50 mg (Standardized to contain 5% Alkaloids)

more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide.

Milg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, Wil 54481

OrthoMolecularProducts.com

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Passarch, Filtese statements have not been evaluated by the,
Food and Drug Administration. This product is not intended
to diagranse, Irrait, cure, or prevent any disease